



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

SEP 17 2002

James Meschino, DC, MS.
President
Nutra Therapeutics International
40 East Main Street
Suite 168
Newark, Delaware 19711

Dear Dr. Meschino:

This is in response to your letter of August 28, 2002 to the Food and Drug Administration (FDA). Your letter was in response to our letter dated July 31, 2002 which was sent in response to your submission to FDA pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

In our previous letter to you we stated that claims you intended to make in the labeling for Glucosamine Joint Formula and Nature's Anti-Inflammatory appeared to be disease claims that suggested that these two products were intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B) and that they were subject to regulation under the drug provisions of the Act. In your current letter, you submitted revised claims that you believe are claims that may be made in the labeling of dietary supplements pursuant to 21 U.S.C. 343(r)(6). We have reviewed your revised claims and continue to believe that certain elements of the claims are disease claims.

The product **Glucosamine Joint Formula** uses the claim "...as a consequence of certain joint injuries, the ability to produce some of the nutrients necessary for normal joint function and cartilage building may decline. This can lead to degenerative changes...which are known to disturb normal joint function and produce varying degrees of discomfort." This claim is a disease claim as defined in 21 CFR 101.93(g); that is, it is a claim that describes "damage to an organ, part, structure, or system of the body such that it does not function properly...a state of health leading to such dysfunctioning."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests

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that it is intended to treat, prevent, or mitigate diseases. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "John B. Foret", with a stylized flourish extending to the right.

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Philadelphia District Office, Office of Compliance, HFR-MA140



August 28, 2002

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and Dietary Supplements
US Food & Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Via Courier

Dear Sirs:

In response to the concerns raised in your letter dated July 31, 2002, we have revised our Glucosamine Joint Formula and our Nature's Anti-Inflammatory labels. A copy of each label is enclosed herein.

Also enclosed is a copy of a label for our FloraZyme product that we are intending to introduce to the marketplace in October 2002.

It is our belief that all of these labels each contain statements allowed for under section 403 (r) (6) of the Federal Food, Drug, & Cosmetic Act.

As President of this company, I hereby certify that the statements made are complete and accurate and our company has substantiation that the statements are truthful and not misleading.

We would appreciate your input with regards to these labels as soon as possible.

Should you require any further information with regards to this matter, please contact me at (888) 251-1010 or by email, jim@nutratherapeutics.com.

Sincerely yours,

Dr. James Meschino DC, MS.
President, Nutra Therapeutics International

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Suggested Supplementation: Adults take one capsule three times daily with meals as a dietary supplement.

Glucosamine Joint Formula provides a pure and stabilized grade of glucosamine sulfate, MSM, and other natural agents that work synergistically to support the structure and integrity of joint cartilage as well as joint mobility. As our bodies age, and as a consequence of certain joint injuries, the ability to produce some of the nutrients necessary for normal joint function and cartilage building may decline. This can lead to degenerative changes within the joint cartilage, which are known to disturb normal joint function and produce varying degrees of discomfort.**


Our unique blend provides proven, natural agents that nourish joint cartilage and help support joint health, with particular application for joints that have undergone degenerative changes to the cartilage structure.**

Do not use if outer seal is broken or missing.

Store in a cool, dry location. Keep out of reach of children.

**The FDA has not evaluated this statement. This product is not intended to diagnose, treat, cure, or prevent disease.





NUTRA THERAPEUTICS

*The Natural Choice of
Healthcare Professionals*

**GLUCOSAMINE
JOINT FORMULA**

• WITH MSM •

• Advanced Formula to Support
Joint Function and Mobility**

DIETARY SUPPLEMENT / 90 CAPSULES

Supplement Facts

Serving Size: 3 Capsules	Servings per Container: 30	
	Amount per Serving	% Daily Value
Glucosamine Sulfate	1,500 mg	*
MSM (Methyl Sulfonyl Methane)	400 mg	*
Quercetin	300 mg	*
Bromelain	300 mg	*
*Daily Value Not Established		

Other Ingredients: Stearic Acid (vegetable source) and gelatin.

Does not contain artificial preservatives, colors, flavors, or added sugar, corn, starch, milk proteins, egg, wheat, yeast, and is not born.

• Guaranteed quality, purity and potency.

Distributed by: Nutra Therapeutics International
40 East Main Street, #166, Newark, DE 19711

For research articles and education visit
www.nutra-therapeutics.com

Suggested Supplementation: Adults take one capsule three times daily with meals as a dietary supplement.

Glucosamine Joint Formula provides a pure and stabilized grade of glucosamine sulfate, MSM, and other natural agents that work synergistically to support the structure and integrity of joint cartilage as well as joint mobility. As our bodies age, and as a consequence of certain joint injuries, the ability to produce some of the nutrients necessary for normal joint function and cartilage building may decline. This can lead to degenerative changes within the joint cartilage, which are known to disturb normal joint function and produce varying degrees of discomfort.**

Our unique blend provides proven, natural agents that nourish joint cartilage and help support joint health, with particular application for joints that have undergone degenerative changes to the cartilage structure.**

Do not use if outer seal is broken or missing.

Store in a cool, dry location. Keep out of reach of children.

**The FDA has not evaluated this statement. This product is not intended to diagnose, treat, cure, or prevent disease.



COPY

JUL 31 2002

James Meschino, D.C., M.S.
President
Nutra Therapeutics International
40 East Main Street
Suite 168
Newark, Delaware 19711

Dear Dr. Meschino:

This is in response to your letter of July 18, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Nutra Therapeutics International is making the following claims, among others, for the following products:

Glucosamine Joint Formula

"...natural anti-inflammatory agents that rebuild cartilage and control the low-grade inflammation of osteoarthritis and joint injuries"

"...block the further destruction of osteoarthritic joints and regenerate damaged joint cartilage"

"...help reduce the swelling and inflammation associated with chronic osteoarthritis and related joint injuries where cartilage damage is present, such as sports injuries"

"Advanced Formula for Relief and Repair of Arthritis and Cartilage Damage"

"With Anti-Inflammatory Herbals"

Nature's Anti-Inflammatory

"...reduce the inflammation and pain of arthritis, bursitis, tendinitis, neuritis, disc herniation, sprains and strains"

"...effective relief of pain and swelling in human studies involving a variety of inflammatory conditions"

"Effective All Natural Relief of Joint and Muscle Inflammation"


21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products (including the use of the term "Anti-Inflammatory" in the name of the product "Nature's Anti-Inflammatory") suggest that they are intended to treat, prevent, cure, or mitigate

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diseases, namely various inflammatory diseases and conditions. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
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Copies:

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FDA, Philadelphia District Office, Office of Compliance, HFR-MA140